

U.S. Patent Application Serial No. 09/964,894  
Amendment filed April 25, 2005  
Reply to OA dated January 26, 2005

**REMARKS**

Claims 4-7 are pending in the application.

In response to the Examiner's objection to the Abstract of the Disclosure, the Applicants have deleted the current Abstract, and submit herewith a substitute Abstract of the Disclosure in place therefor. No new matter has been added.

In view of the remarks set forth below and the attached 37 CFR § 1.132 Declaration, further and favorable consideration is respectfully requested.

**Claims 4-7, have been rejected under 35 USC § 103(a), as being unpatentable over Anazawa et al. (US Patent No: 5,192,320) in view of Kashiwabara et al (EP-1057492) and Motomura et al. (EP-0769503). (Office Action p.4)**

Anazawa is directed to an artificial lung and a method of using it. The artificial lung performs the exchange of gases between blood and a gas through a homogeneous membrane by passing blood over one side of the membrane and oxygen over the other side. The membrane is a hollow fiber membrane composed of polyolefin and has an oxygen flux of at least  $1 \times 10^{-6}$  and more preferably  $5 \times 10^{-5}$  to  $1 \times 10^{-3}$  ( $\text{cm}^3(\text{STP})/(\text{cm}^2 \cdot \text{sec} \cdot \text{cmHg})$ ).

Claim 4 was amended in the previous response, dated November 22, 2004, to recite an oxygen permeation rate  $Q(\text{O}_2)$  at  $25^\circ\text{C}$  of from  $5 \times 10^{-4}$  to  $2 \times 10^{-3}$  ( $\text{cm}^3(\text{STP})/(\text{cm}^2 \cdot \text{sec} \cdot \text{cmHg})$ ), a range which has unexpected results over the prior art.

The attached Declaration describes the creation of two artificial lungs X1 and Y1 according

to the Declaration, Synthesis Example 1 on p.19 and Example 1 on p.31 of the specification. In addition, artificial lung Z1 was created in the same manner as Synthesis Example 1 and Example 1 of the specification except that the gas permeation rate, determined in accordance with the pressure method as defined in ASTM D1434, was  $4.0 \times 10^{-4} \text{ cm}^3(\text{STP})/(\text{cm}^2.\text{sec.cmHg})$ .

Fig. A on p.7 of the Declaration shows the results of the carbon dioxide eliminating capacity of all three lungs X1 ■, Y1 ♦ and Z1 ▲ as well as an oblique straight reference line indicating the AAMI standard for blood-gas exchange.

The tests show that an artificial lung Z1, with a hollow fiber membrane having an oxygen permeation rate lower than  $5.0 \times 10^{-4} \text{ cm}^3(\text{STP})/(\text{cm}^2.\text{sec.cmHg})$ , had an insufficient  $\text{CO}_2$ - removing amount and thus was not usable for clinical purposes. In contrast, artificial lungs X1 and Y1 being a hollow fiber membrane having an oxygen permeation rate within the claimed range were capable removing  $\text{CO}_2$  as indicated by the points, X1 ■, Y1 ♦, above the AAMI line in Fig. A on p.7.

These results were unexpected because the prior art, particularly Anazawa, disclosed broad permeability ranges, which as shown in the Declaration, are in fact not clinically practical. There is nothing in Anazawa to indicate that oxygen permeation rates lower than  $5.0 \times 10^{-4} \text{ cm}^3(\text{STP})/(\text{cm}^2.\text{sec.cmHg})$ , have an insufficient  $\text{CO}_2$ - removing ability. Anazawa does in fact disclose a chemically different artificial lung and the Declaration shows empirically that drawing a conclusion of obviousness from a chemically different lung does not logically follow, as will be further explained.

The results of the Declaration make clear that the broad ranges disclosed in Anazawa, *with*

U.S. Patent Application Serial No. 09/964,894  
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*no further teaching*, do not at all make obvious the invention as now claimed because the Declaration shows that ranges lower than  $5.0 \times 10^{-4} \text{ cm}^3(\text{STP})/(\text{cm}^2 \cdot \text{sec} \cdot \text{cmHg})$  do not perform. Thus, combinations of general disclosures in the prior art, with out any guide to more specific workable ranges, do nothing to lead the skilled artisan to the invention as now claimed.

Based on a lack of disclosure, one cannot logically conclude the invention as now claimed is obvious. Furthermore Kashiwabara fails to suggest the claimed surface coating and its combination with Anazawa, which also does not teach the surface coating (Office Action p.4, text lines 15-16) and Motomura ("Further, while it is true Motomura does not disclose the material claimed..." Office Action dated April 19, 2004, p.2, text line 11) cannot logically make the claimed invention obvious under 35 USC 103.

Therefore, the combination of Anazawa with Kashiwabara and/or Motomura, again does not follow because there is no motivation or suggestion, supporting the combination, to teach the invention as now claimed. The Declaration shows the *unexpected results* of the invention as now claimed. These results are nowhere shown or even suggested in the prior art. The prior art fails to indicate that oxygen permeation rates lower than  $5.0 \times 10^{-4} \text{ cm}^3(\text{STP})/(\text{cm}^2 \cdot \text{sec} \cdot \text{cmHg})$ , have an insufficient  $\text{CO}_2$ -removing ability. Simply put, without more, the rejection of obviousness must fail.

In view of the aforementioned amendments and accompanying remarks, the claims, as amended, are in condition for allowance, which action, at an early date, is requested.

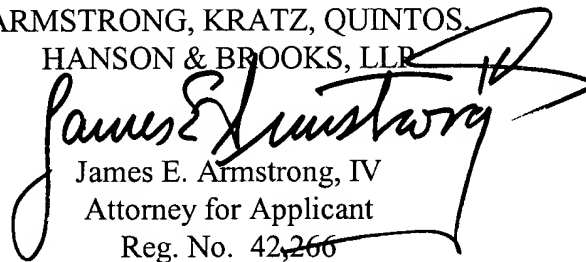
U.S. Patent Application Serial No. 09/964,894  
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If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact Applicants undersigned attorney at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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Enclosures: Substitute Abstract of the Disclosure (1 page)  
37 CFR § 1.132 Declaration (9 pages)

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